

RUSS, AUGUST & KABAT

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10 **UNITED STATES DISTRICT COURT**
11 **CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION**
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13 NEUROGRAFIX, a California
14 corporation; WASHINGTON
15 RESEARCH FOUNDATION, a not-for-
16 profit Washington corporation,

17 Plaintiffs,

18 vs.

19 SIEMENS MEDICAL SOLUTIONS
20 USA, INC., a Delaware corporation; and
21 SIEMENS AKTIENGESELLSCHAFT, a
22 German Corporation,

23 Defendants.
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26
27
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Case No. 10-CV-1990 MRP (RZx)

[Assigned to The Honorable Mariana
R. Pfaelzer]

**REBUTTAL EXPERT REPORT OF
MICHAEL N. BRANT-
ZAWADZKI, M.D., F.A.C.R TO
THE EXPERT REPORT OF DR. R.
NICK BRYAN CONCERNING U.S.
PATENT NO. 5,560,360**

First Amended Complaint Filed:
July 30, 2010

TABLE OF CONTENTS

I.	SUMMARY OF OPINIONS	1
II.	INTRODUCTION.....	2
III.	MY QUALIFICATIONS	2
IV.	SUMMARY OF MY OPINION REGARDING THE "CONSPICUITY" TERM TO A PERSON OF ORDINARY SKILL IN THE ART IN LIGHT OF THE '360 PATENT	2
V.	RESPONSES TO THE SPECIFIC OPINIONS PROVIDED BY DR. BRYAN	4
A.	Dr. Bryan's Opinions Regarding "Conspicuity In General" (¶¶ 21-27)	4
B.	Dr. Bryan's Opinion Regarding "Regions of Interest in General."	5
C.	Dr. Bryan's Conspicuity Analysis and Exemplary Calculations Are Not Applicable to How One of Ordinary Skill in the Art Would Calculate Conspicuity in Light of the Disclosures of the '360 Patent	10

**REBUTTAL EXPERT REPORT OF MICHAEL N. BRANT-ZAWADZKI,
M.D., F.A.C.R. TO THE EXPERT REPORT OF DR. R. NICK BRYAN
CONCERNING U.S. PATENT NO. 5,560,360**

I. SUMMARY OF OPINIONS.

1. This report sets forth my responses to the opinions set forth by Dr. R. Nick Bryan in his expert report, dated July 22, 2011.

2. I disagree with Dr. Bryan that one of ordinary skill in the art would not have been able to discern the meaning of the term "conspicuity of 1.1" used in the '360 patent, and that one of ordinary skill in the art would reach different conclusions about whether a particular MR image meets the required "conspicuity of 1.1."

3. Further, it is my opinion that, in light of the teachings of the '360 patent, a person of ordinary skill in the art at the time of filing would have understood that conspicuity is determined by selecting a region of interest ("ROI") in, and measuring the average signal intensity of the nerve of interest and likewise ROI and the average signal intensity of the nearby non-neural tissue. One of skill in the art at the time would have also understood that conspicuity, as defined in the '360 patent, is calculated then taking the ratio of the average signal intensities for the two ROIs.

4. It is also my opinion that one of skill in the art at the time of filing would have been apprised of the scope of the claims because the '360 patent provides one of skill in the art with sufficient guidance for identifying the nerve and adjacent or surrounding non-neural tissue and selecting the two regions of interest. I have the same opinion with respect to the phrase "the nerve at an intensity of at least 5 times that of the non-neural tissue."

5. I base my opinion on Dr. Bryan's expert report, the materials considered by Dr. Bryan, the materials listed in Exhibit A to this report, and the materials listed in Exhibit B to my July 21, 2011 opening expert report as well as the materials

1 cited below. These materials include the '360 patent, including its prosecution
2 history, the parties' previous claim construction briefs, the Court's Claim
3 Construction Order, Dr. Bryan's expert report and my 35 years of experience and
4 knowledge as a diagnostic radiologist and neuroradiologist

5 **II. INTRODUCTION.**

6 6. I have been asked to review Dr. Bryan's expert report and provide my
7 opinions in response to his report. In particular, I have been asked to assess, in
8 light of the disclosure of the '360 patent, whether I agree with the opinions
9 expressed by Dr. Bryan.

10 **III. MY QUALIFICATIONS.**

11 7. My qualifications for forming the opinions set forth in this rebuttal expert
12 report were summarized in my opening expert report, served on July 21, 2011.

13 **IV. SUMMARY OF MY OPINION REGARDING THE** 14 **"CONSPICUITY" TERM TO A PERSON OF ORDINARY** 15 **SKILL IN THE ART IN LIGHT OF THE '360 PATENT.**

16 8. I provide a detailed analysis of my opinions regarding how a person of
17 ordinary skill in the art in light of the '360 patent will understand how to calculate
18 conspicuity in my previous expert report. In my opinion, Dr. Bryan's expert
19 report fails to take into account the disclosure of the '360 patent as well as the
20 training and experience of a person having ordinary skill in the art. While many
21 of Dr. Bryan's opinions may be correct in a general sense, it is my understanding
22 that the appropriate analysis must be made in light of how one of ordinary skill in
23 the art after reading the '360 patent, including the file history, would understand
24 the "conspicuity" term. For the sake of brevity, I summarize my opinions below.

25 9. In light of the '360 patent, a person of ordinary skill will understand that
26 conspicuity is calculated by taking the average signal intensity of the nerve
27 divided by the average signal intensity of non-neural tissue. *See* ¶ 26 of my
28 opening report. A person of ordinary skill in the art will understand how to

1 identify nerves in an MR image based on the disclosure in the '360 patent and
2 their training and experience. In particular, a person of ordinary skill will use one
3 or more of the following techniques: 1) their extensive training and experience in
4 identifying anatomy on MR images, including nerves; 2) the presence of a
5 fascicle pattern; and/or 3) diffusion anisotropy and fat suppression. *See* ¶¶ 28-35
6 of my opening report. I discuss each of these techniques in detail in my opening
7 report. *Id.*

8 10. Similar to the identification of a nerve on an MR image, it is also my
9 opinion that one having ordinary skill in the art will understand how to select the
10 appropriate regions of interest to be used in the conspicuity calculation. *See* ¶¶
11 35-45 of my opening report. Radiologists are extensively trained and experienced
12 in selecting a region of interest that includes only the structure they are interested
13 in. Where the structure is homogenous, as nerves often appear on an MR image
14 made using the method of the '360 patent, a person of ordinary skill in the art who
15 is asked to calculate conspicuity according to the disclosure of the '360 patent will
16 select a representative portion within the nerve and the appropriate nearby non-
17 neural tissue. Where the structure is heterogenous, such as if fascicle pattern can
18 be seen, a person of ordinary skill in the art will select the largest possible
19 representative portion of the entire structure in the MR image. The selection of
20 the largest representative portion of the nerve is guided by using a thresholding
21 process described in the specification of the '360 patent at column 28, lines 2 to 7.
22 For those claims in the '360 patent that require fascicle analysis or suppression of
23 non-fascicle data, a radiologist will know to follow the dictates of the '360 patent
24 at column 28, lines 8-16 or column 28, lines 19-22, respectively.

25 11. Indeed, the method Dr. Bryan used to select regions of interest in Exhibit C
26 of his expert report illustrates exactly the methods I discussed in my opening
27 report. However, the non-neural tissue structures that Dr. Bryan selected in
28 Exhibit C of his report are not consistent with how one of ordinary skill in the art

1 would select the regions of interest in light of the disclosure of the '360 patent.
2 For example, in Figures 1 and 2 of Exhibit C, Dr. Bryan selects three portions of
3 the nerve and then intentionally selects non-neural tissue from various places
4 throughout the MR image. In light of the '360 patent, a person of ordinary skill in
5 the art would select structures in close proximity to the nerve, *i.e.*, surrounding or
6 adjacent to the nerve, not structures from anywhere on a given image. Dr. Bryan
7 shows the same selection bias in Figures 4 and 5 of Exhibit C. In addition, in
8 Figure 5 of Exhibit C, Dr. Bryan alleges to be calculating the conspicuity of nerve
9 compared to adjacent non-neural tissue. It is not clear, however, what Dr. Bryan
10 selected in this figure. Although I believe that the regions of interest chosen by
11 Dr. Bryan in Exhibit C of his report are inconsistent with the intent of the
12 "conspicuity" term, I note that he had no problem using his experience and
13 training to select representative neural and non-neural tissue regions of interest to
14 support his opinion.

15 **V. RESPONSES TO THE SPECIFIC OPINIONS PROVIDED BY**
16 **DR. BRYAN.**

17 **A. Dr. Bryan's Opinions Regarding "Conspicuity In General"**
18 **(¶¶ 21-27)**

19 12. The section of Dr. Bryan's report addressing "conspicuity in general" does
20 not address the "conspicuity" term as it is used in the '360 patent. This is further
21 confirmed by the title of the next section, which refers to "'conspicuity' in the '360
22 patent." Because these opinions do not account for the disclosure of the '360
23 patent or the holdings in the Court's Claim Construction Order, I do not believe
24 any of these opinions are relevant to the question at hand.

25 13. As I discussed in my opening report, the '360 patent provides a specific
26 formula for calculating conspicuity: $\text{Conspicuity} = \text{Contrast} = S_n/S_b$ (where S_b is
27 the non-neural tissue required by the particular claim.).
28

14. Although Dr. Bryan admits that the formula for conspicuity is disclosed in the '360 patent, Dr. Bryan criticizes the inventors' formula because it does not account for noise. (Bryan Report at ¶¶ 24-27). As an initial matter, this criticism is irrelevant because, as it has been explained to me, patent law allows the inventors to define their own meanings for terms as long as the alternative meaning is expressly disclosed. Also, as Dr. Bryan acknowledges, the term conspicuity can be defined differently for specific types of imaging instrumentation and technique.

15. Additionally, the patent expressly explains that images made using the disclosed method have little noise. See '360 patent at 6:38-46 ("Surprisingly, the inventors have discovered that there are certain novel ways of assembling complex pulse sequences, wherein even though the simple components of the sequence decrease the signal-to-noise ratio of nerve or decrease the signal strength of nerve relative to other tissues, the fully assembled complex sequence actually results in the nerve signal being more intense than any other tissue."). Indeed, as shown in Exhibit B, the images provided by Dr. Filler that Dr. Bryan uses do indeed have little noise.

16. Further, even if noise were in fact a problem in an image, the conspicuity calculation in light of the '360 patent requires the use of structures in close proximity to each other on a single image. As such, the noise levels will be practically the same for both nearby structures and will effectively cancel out of any calculation accounting for noise.

B. Dr. Bryan's Opinion Regarding "Regions of Interest in General."

17. As I have discussed above and in my opening report, in the context of the disclosure of the '360 patent and its claims, a person of ordinary skill in the art will understand how to select the required regions of interest to perform the conspicuity calculation required by the "conspicuity" term.

18. In ¶¶ 29-34, Dr. Bryan opines extensively regarding the various ways general radiological literature has defined selecting regions of interest for the study they are reporting. Indeed, each journal article cited in ¶¶ 29-34 of Dr. Bryan's report discusses methods of selecting of regions of interest that are applicable to a particular study, *e.g.*, measurement of brain tumors, brain lesions, breast tumors, etc. The anatomical structures examined in the articles are not comparable to the nerves listed in the '360 patent claims, which may have fascicles within the tissue that appear as alternating bright and dark portions, similar to a checkerboard. In fact, none of these studies relate to selecting regions of interest to study the conspicuity of a nerve using the method taught in the '360 patent. Tellingly, Dr. Bryan does not opine that any of the methods discussed in the journal articles is applicable to selecting a region of interest in a nerve that accounts for the presence of fascicles to determine whether it is 1.1 times more conspicuous than surrounding or adjacent non-neural tissue.

19. Furthermore, as I note above, despite his lengthy discussion regarding the various methods a radiologist could use to select a region of interest, Dr. Bryan ultimately adopts and uses the same method that I describe in my opening report. This lends further support to my opinion that a person having ordinary skill in the art will know how to calculate conspicuity.

20. In ¶¶ 30, 32 & 39, Dr. Bryan opines that measurement of an ROI depends upon the composition of pixels included in the ROI. I find Dr. Bryan's assessment moot in light of the disclosure of the '360 patent. As a preliminary matter, a structure will typically appear homogenous in an MR image. In other words, the signal intensity will be relatively uniform throughout the entire structure. An example of this is shown in Fig. 1a of E.A. Vokurka et al., Improved High Resolution MR Imaging for Surface Coils Using Automated Intensity Non-Uniformity Correction: Feasibility Study in the Orbit in *Journal of Magnetic Resonance Imaging* 14:540-546 (2001), which was reproduced in ¶ 43

1 of my opening expert report. When a person of ordinary skill selects an ROI
2 within a homogenous structure, the average signal intensity of the ROI will not
3 vary significantly based on the size, shape, or position of the ROI selected.

4 21. Further, where the structure is heterogenous, such as if fascicle pattern can
5 be seen, a person of ordinary skill in the art will select the largest representative
6 portion of the entire structure within the boundary. The claims themselves dictate
7 this, because they require taking the average signal intensity of the "nerve," not a
8 portion of the nerve. In addition, the patent specification describes a specific
9 method for choosing a region of interest. In particular, the patent discloses to use
10 "a threshholding process to identify relatively bright regions of the image
11 potentially representative of nerve.¹ With the boundaries of these regions
12 established, the intensity of the pixels associated with each region is evaluated
13 and average image intensities for the regions are computed." '360 patent at 28:2-
14 7. Using a thresholding process based on brightness will typically result in the
15 largest possible region of interest inside the anatomical boundary of the nerve. In
16 addition, as the patent notes, the thresholding process will distinguish nerve from
17 non-neural tissue. *Id.* at 28:17-19. Therefore, I disagree with Dr. Bryan's opinion
18 in ¶ 35 that nothing in the '360 patent indicates a precise method for selecting the
19 appropriate region of interest.

20 22. I also disagree with Dr. Bryan's opinion that a radiologist's selection of the
21 relevant regions of interest to use in the calculation of conspicuity in light of the
22 '360 patent depends on his or her ability to distinguish the boundary between the
23 two structures. (Bryan Report ¶¶ 36, 38) As I discuss above, the identification of
24 the exact boundaries of the nerve is not relevant to the conspicuity analysis
25 disclosed in the '360 patent because a radiologist will select ROIs that will only

26 _____
27 ¹ As the absolute signal intensity of structures on an MR image varies with each image, the
28 inventors could not have defined a specific threshold. A person of ordinary skill, however,
would understand how to select the appropriate threshold for a particular image.

1 include the structure they are interested in, and will seek to exclude voxels which
2 they believe may not actually be part of the structure. As in E.A. Vokurka et al.,
3 Improved High Resolution MR Imaging for Surface Coils Using Automated
4 Intensity Non-Uniformity Correction: Feasibility Study in the Orbit in *Journal of*
5 *Magnetic Resonance Imaging* 14:540-546 (2001), which discusses correcting for
6 non-uniformity artifacts, so long as the person of ordinary skill in the art can
7 select the largest representative region within the relevant tissue with confidence,
8 the actual boundaries are irrelevant. Indeed, if, as Dr. Bryan suggests in ¶ 36, the
9 image clues are so poor that a person of ordinary skill cannot be sure of where the
10 neural tissue is, such an image would not meet the conspicuity requirement of the
11 claims of the '360 patent. A person of ordinary skill need only be able to select
12 representative portions of the structure. Second, the '360 patent expressly teaches
13 how to identify nerves. If a person of ordinary skill in the art is unsure whether a
14 particular structure is nerve, they can and should use one of these techniques to
15 identify the nerve.

16 23. Further, it is unclear what is meant by Dr. Bryan's statement that "[it] is
17 entirely possible that an image could inherently have a [conspicuity] of 1.1, but
18 that the nerves cannot be reliably distinguished from other tissues." Bryan Report
19 ¶ 38. First, an MR image would not have conspicuity. Second, if a radiologist
20 cannot distinguish the nerve from other non-neural tissues, then he or she will
21 know that the "conspicuity" limitation is not met.

22 24. I strongly disagree with Dr. Bryan's opinion expressed in ¶ 37 of his report.
23 When a radiologist performs an MRI study to diagnose and treat a patient, he or
24 she will tailor the exam to target a specific region of interest that is of clinical
25 concern. If a radiologist orders an exam to visualize nerves using the claimed
26 method in the '360 patent, the radiologist should know where to locate the nerve
27 of interest within the MRI study; and, most often, the nerve is in the expected and
28 normal location. As discussed above, in the rare circumstance when the nerve

1 may not be in the expected location or not readily identifiable, a radiologist would
2 rely on tracing the course from a normal identifiable position along the course of
3 the displaced anatomy, the presence of a fascicle pattern, and/or the combination
4 of diffusion anisotropy and fat suppression to identify the nerve. '360 patent at
5 22:33-36 ("The combined use of fat suppression and diffusional weighting has,
6 however, been found to be extremely effective in providing the desired nerve
7 enhancement."). Radiologists are extensively trained, and are expected, to
8 understand and read MR images, to treat and diagnose patients. This is the very
9 reason that radiology is a specialty within medicine.

10 25. I also disagree with ¶ 39 of Dr. Bryan's report because the inventors of the
11 '360 patent could not have specified the size, shape or position of a region of
12 interest in the claims. As shown in Exhibit C to Dr. Bryan's report, nerves do not
13 have a specific size or shape and these features also change depending on a
14 number of factors, including the view used to view them (sagittal, coronal, etc.).

15 26. Dr. Bryan's opinion in ¶ 40 of his report regarding segmentation algorithms
16 is irrelevant because a person of ordinary skill in the art will not need to
17 determine precisely the boundaries of the nerve and non-neural tissue to perform
18 the conspicuity calculation. A radiologist is well trained in selecting regions of
19 interest and will know how to avoid selecting blurry voxels that contain multiple
20 tissues. As discussed above, a radiologist will select a region of interest that is
21 clearly within the boundary of the nerve or surrounding or adjacent tissue.
22 Indeed, this is a common place, if not an everyday, task for an average
23 radiologist.

C. Dr. Bryan's Conspicuity Analysis and Exemplary Calculations Are Not Applicable to How One of Ordinary Skill in the Art Would Calculate Conspicuity in Light of the Disclosures of the '360 Patent.

27. Dr. Bryan's characterization of Exhibit A to Dr. Filler's Rebuttal Report and Dr. Filler's selection of ROIs in ¶ 43 does not affect my opinion that one of skill in the art would be able to determine whether the claims of the '360 patent are being practiced or not. The region of interest selections made by Dr. Filler in his rebuttal report were made in response to Dr. Moseley's arguments and were intended to demonstrate that whether one calculates conspicuity by the mean, min, max, or max-min signal intensity, at least one pane in a study will have a nerve conspicuity 1.1 times non-neural tissues. Filler Rebuttal Report ¶ 48. Thus, it is irrelevant that Dr. Filler did not select smaller peripheral nerves or nerves that would lead to conspicuity calculations of less than 1.1 because it was clear that a nerve in the pane, the brachial plexus, met the "conspicuity of 1.1" claim limitation.

28. I disagree with the opinions Dr. Bryan expressed in ¶¶ 43-44 of his report regarding which and how many nerves and non-neural tissue to select. The claim language requires that the nerve that is selected be "a nerve" that has had its selectivity enhanced by the method. *See* '360 patent at claim 1. I have been informed and understand that it is well established that "a" means "one or more" in patent law. Thus, in my opinion, showing a conspicuity of a single nerve on an MR image is sufficient.

29. I also disagree with Dr. Bryan's opinion that the non-neural tissue relevant to the conspicuity analysis is not well defined. As discussed above and in my opening report, it is my opinion that a person having ordinary skill in the art would have understood that the proper method to determine conspicuity was to use the ratio of average signal intensity from the nerve as identified by the

1 observer over the average signal intensity of the surrounding or adjacent non-
2 neural tissue, as selected by the observer. If asked to determine whether a nerve
3 in an MR image meets the "conspicuity of 1.1" limitation, a practicing radiologist
4 would compare the brightness of the nerve to that of the surrounding or adjacent
5 non-neural tissue rather than to all non-neural tissue in the image. My
6 disagreement with Dr. Bryan's position is shown in his application of it, such as in
7 Figure 1 of Exhibit C to his report. If a person of ordinary skill in the art, in light
8 of the disclosure of the '360 patent, were asked to calculate conspicuity, they
9 would not select regions of interest far away from the nerve. In order to
10 determine whether the nerve was conspicuous (*i.e.*, readily distinguishable from
11 its surroundings), a person of ordinary skill in the art would select non-neural
12 tissue either adjacent (as in claim 18) or immediately surrounding the nerve (as in
13 claim 3) or in relation to a fascicle analysis (as in claim 1).

14 30. Further, I disagree that the conspicuity calculation is "unworkable"
15 whenever the nerve is not readily identifiable. As discussed above, a radiologist
16 can identify the majority of nerves of interest targeted by the MR study by one or
17 more of the following techniques: knowledge of gross anatomy, the presence of a
18 fascicle pattern, and/or the combination of diffusion anisotropy and fat
19 suppression. If, however, the nerve cannot be identified using these techniques,
20 that nerve cannot be used as a basis for the conspicuity calculation.

21 31. Dr. Bryan's opinion that a radiologist could select ROIs in the nerve and
22 surrounding tissue in an MR image that would result in conspicuities of both less
23 than 1.1 and greater than 1.1 is irrelevant. (Bryan Report ¶¶ 45-58) As discussed
24 above, if an average radiologist is asked to determine whether the nerve has a
25 conspicuity of at least 1.1 times as defined in the '360 patent, a radiologist would
26 select ROIs that are representative of the nerve and representative of the
27 surrounding or adjacent tissue. *See* 1 David D. Stark & William G. Bradley, Jr.,
28 Magnetic Resonance Imaging 24 (2d ed. 1992) ("The *signal* is the mean intensity

1 within a region of interest (ROI) over a certain tissue."). Therefore, a radiologist
2 would not select an ROI of the nerve or surrounding tissue consisting of any
3 random single pixel within the nerve unless the single pixel represents the entire
4 nerve or surrounding tissue, which is rarely the case. Similarly, a radiologist
5 would not select an ROI consisting of an isolated group of the darkest pixels in a
6 bright nerve or an isolated group of the brightest pixels in a dark non-neural
7 tissue. In addition, a radiologist would select an ROI that includes only the
8 structure of interest, and will seek to exclude voxels which they believe are not
9 actually part of the structure. In fact, the signal intensities of most nearby
10 structures, such as fat, are suppressed in MR images made using the methods of
11 the '360 patent. Further, the identification and selection of nerve and non-neural
12 tissue is a teachable, well-known, repeatable skill for radiologists. In my opinion,
13 average radiologists would have no problem determining conspicuity relevant to
14 the claims of the '360 patent in a consistent and repeatable manner and therefore
15 be able to determine whether the claims of the '360 Patent are being practiced or
16 not.

17 32. I disagree with Dr. Bryan's opinions in ¶¶ 54-56 because they do not reflect
18 how a person of ordinary skill in the art in light of the '360 patent will choose the
19 nerve and non-neural tissue regions of interest to calculate conspicuity. As I
20 discuss above, an average radiologist asked to perform the conspicuity calculation
21 will not likely choose any of the regions of interest chosen by Dr. Bryan.
22 Because I observe that Dr. Bryan intentionally did not choose nearby non-neural
23 tissue in Figures 1-4 of Exhibit C that were in close proximity or adjacent to the
24 neural region of interest he chose, it is my opinion that Dr. Bryan may have
25 ignored his training and experience in order to take an intentionally contrarian
26 position for the sake of argument. As I understand the law, a person of ordinary
27 skill is not influenced by such argumentative or litigation-oriented concerns.
28

RUSS, AUGUST & KABAT

33. In addition, Dr. Bryan shows the same argumentative bias in Figures 6-8 of Exhibit C by purposefully selecting regions of interest that are from portions of the nerve that are going outside the plane of the image and, therefore, appear darker than the rest of the nerve that are inside the plane of the image. The small regions of interest selected also contain fascicles that accounts for the variation in signal intensity. As discussed above, unlike Dr. Bryan, a person of ordinary skill in the art will select the entire relevant structure in the MR image rather than just a small portion of the nerve if fascicles exist in the structure.

34. I further note that the only conspicuity measurement Dr. Bryan made that is consistent with the adjacent non-neural tissue limitation of claim 18 is Figure 5 and ¶ 57. As I discussed above, although Dr. Bryan represents he is selecting nerve and non-neural tissue, I cannot tell what structures Dr. Bryan is selecting.

I declare under penalty of perjury that the statements in this report are true and correct.

Executed on August 8, 2011 in Newport Beach, California.

By:

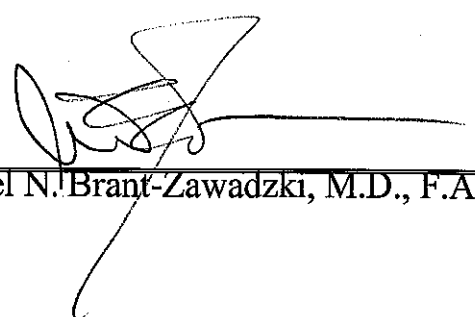
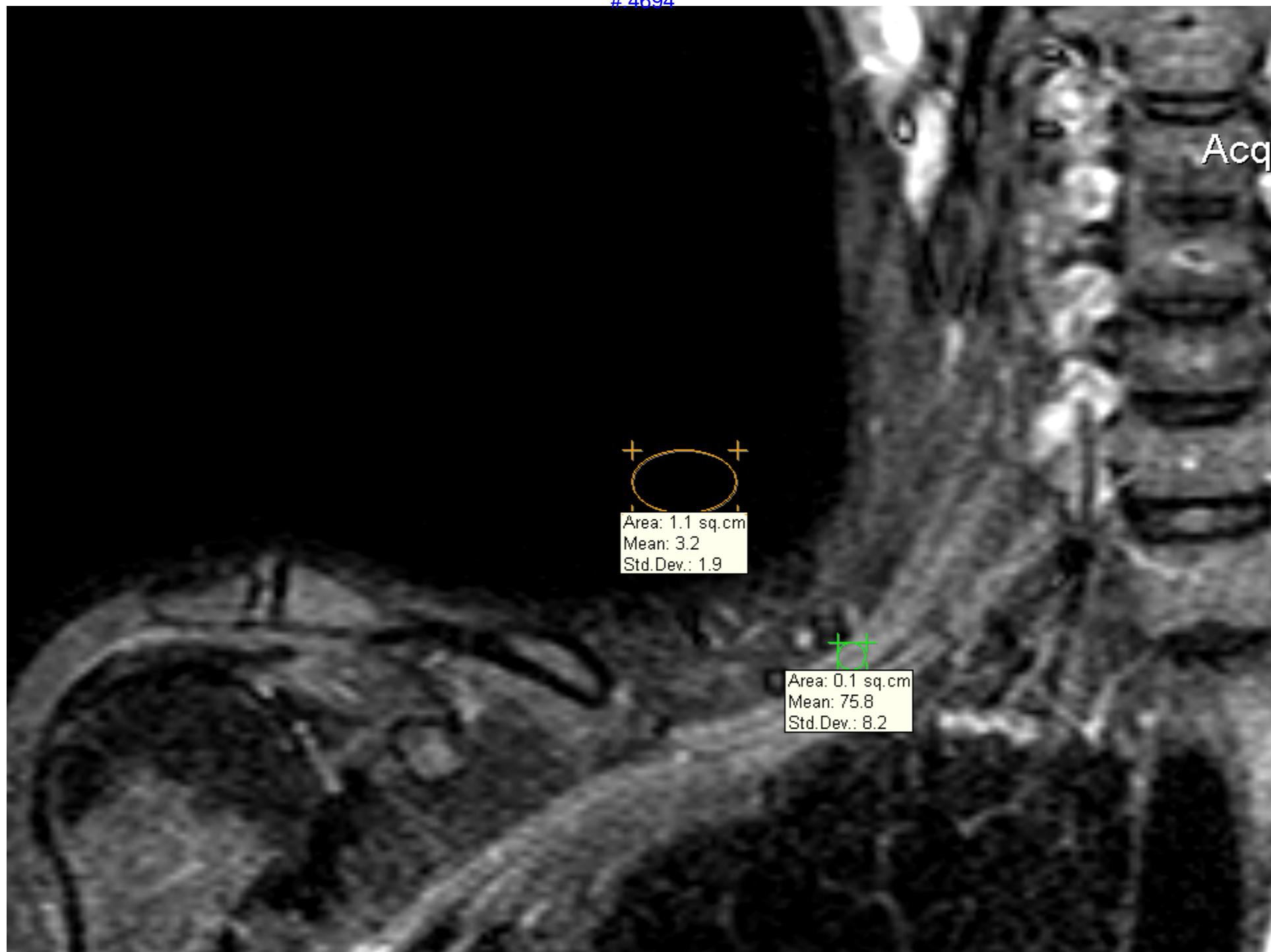

Michael N. Brant-Zawadzki, M.D., F.A.C.R.

EXHIBIT A

Materials Considered

1. All the materials listed in Exhibit A to my July 21, 2011 Opening Expert Report
2. Expert Report of Dr. Nick R. Bryan Concerning the Term "Conspicuity" in U.S. Patent No. 5,560,360 and Exhibits, dated July 22, 2011
3. 1 David D. Stark & William G. Bradley, Jr., Magnetic Resonance Imaging 24 (2d ed. 1992)

Exhibit B



Ex: 23
ExhC Axial STIR
Se: 8256/1
Im: 1/1
Ax: 136.7 (COI)

ExhibC
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Acc: 58
2011 Mar 10
Acq Tm: 10:22:01.000000

Mag: 5.1x

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ET: 0
TR: 0.0
TE: 0.0

